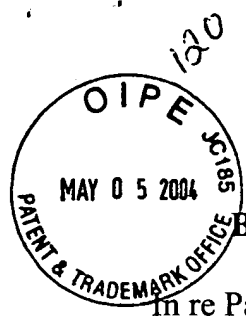


AF/3762



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

In re Patent Application of

OLDHAM

Atty. Ref.: 39-236;
Confirmation 4610
Group: 3762
Examiner: G. Evanisko

Serial No. 09/815,297

Filed: March 23, 2001

For: STIMULATION OF MUSCLES

May 5, 2004

Mail Stop Appeal Brief - Patents
Commissioner for Patents
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Alexandria, VA 22313-1450

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CORRECTED APPEAL BRIEF

Sir:

Applicant hereby appeals to the Board of Patent Appeals and Interferences from a Final Action dated June 25, 2003. A Notice of Appeal was filed November 24, 2003. A Petition is made for a one month extension of time, with the appropriate fee.

This corrected brief is being filed to overcome the objections to the original brief cited in the Notification of Non-Compliance dated April 28, 2004. The objections made to the original brief have been overcome as suggested in the Notification. With respect to the objection made to the reproduced figures in the body of the argument, those figures have been clearly indicated as being "annotated" so as to avoid any confusion with the figures of this application.

REAL PARTY IN INTEREST

The real party in interest is The Victoria University of Manchester a corporation of Great Britain.

RELATED APPEALS AND INTERFERENCES

The appellant, the undersigned, and the assignee are not aware of any related appeals or interferences which will directly affect or be directly affected by or have a bearing on the Board's decision in this appeal.

STATUS OF CLAIMS

Claims 1 to 10, 12 and 16 are pending and have been rejected.

Claims 11 and 13 to 15 have been allowed.

STATUS OF AMENDMENTS

An Amendment After Final Rejection was filed on February 12, 2004 (shortly before this brief was filed) and has been entered.

SUMMARY OF INVENTION

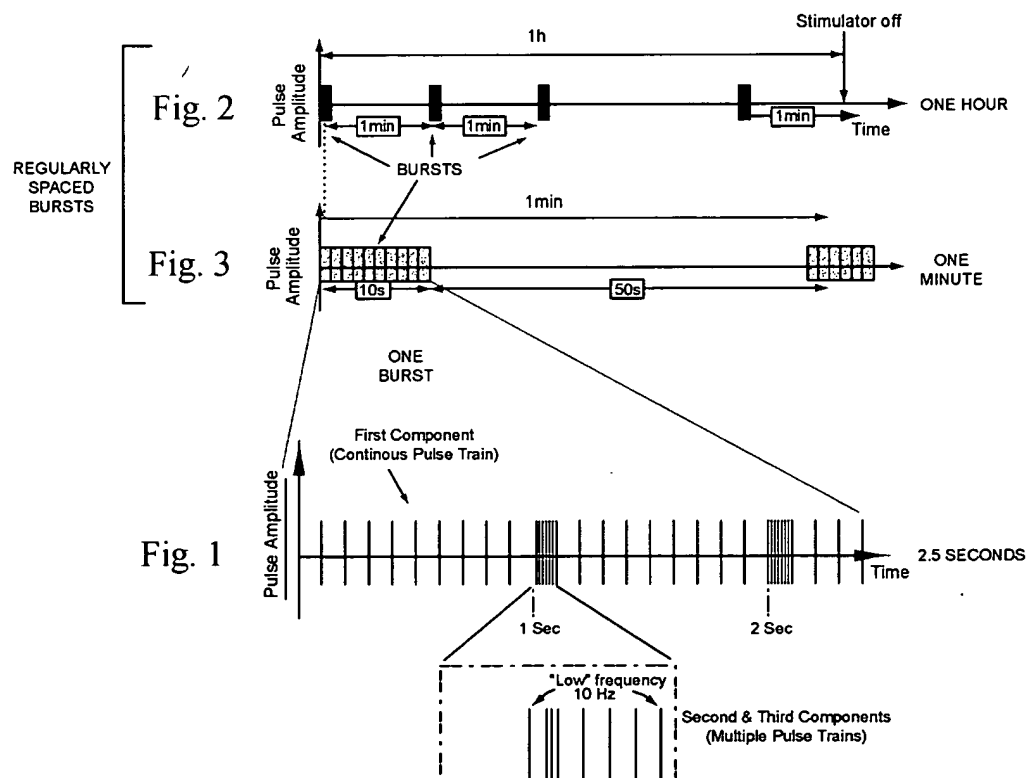
The invention is an electrical muscle stimulator (11) that applies regularly spaced bursts (pulses 1 to 8) of stimulation pulses to the skin of patient. Spec. p. 4, ln. 24 to p. 5, ln. 6. The pulses are applied by the stimulator to provide health benefits, such as improving muscle strength. Spec. p. 2, lns. 3-8.

The specification states that:

pulse bursts can be delivered for 'on' times of from ten to fifty seconds, with periods of inactivity, i.e. 'off' times, of approximately the same duration. Good results have been obtained with "on" times of ten seconds in combination with 'off' times of fifty seconds. [Spec. p. 8, last line to p. 9, ln. 12.]

Figures 2 and 3 of the specification illustrates a series of pulse "bursts" that are separated by intervals of "off" time. Figures 1 to 3 are reproduced below, and have been annotated and revised better illustrate that bursts repeat and that each burst includes multiple pulse trains. Figures 2 and 3 show spaced apart bursts. Figure 1 shows an individual burst and the trains of pulses that constitute the burst.

The following figures are annotated versions of Figures 1, 2 and 3 of the application. The figures below have been annotated to clearly identify the regularly spaced bursts in figures 2 and 3, and the single burst shown in figure 1.



Annotated figure 1 above shows a single burst having a continuous train (the first train) of low-frequency pulses on which is superimposed multiple high-frequency pulse trains (second trains). Each burst includes a first component that is a continuous series of regularly spaced pulses, and a second component that is multiple trains of regularly spaced pulses. The spacing (frequency) between the pulses of the second component is less than the spacing between the pulses of the first component. Spec., p. 4, ln. 22 to p. 8, ln. 12; p. 8, lns. 1-20.

Preferably, each burst further includes a series of regularly spaced third trains of regularly spaced pulses. Each burst of pulses may consist of the same number of second and third pulse trains and preferably each third pulse train immediately precedes a respective second pulse train. Spec. p. 4, ln. 22 to p. 8, ln. 12, *see also* Group II claims.

STATEMENT OF ISSUES ON APPEAL

1. Whether the electrical muscle stimulator recited in independent claims 1 and 16, dependent claims 2 to 10 and 12 are anticipated (35 U.S.C. §102) by or would have been obvious (35 U.S.C. §103) in view of the muscle stimulation device disclosed in Cywinski (US Patent 5,350,415).

2. Whether the electrical muscle stimulator recited in independent claims 1 and 16 and dependent claims 2 to 10 and 12 are anticipated (35 U.S.C. §102) by or would have been obvious (35 U.S.C. §103) in view of the muscle stimulation device disclosed in Campos (US Patent 5,097,833).

GROUPING OF CLAIMS

GROUP I - Includes independent claim 1, claims 8, 9 10 and 12 (which depend on claim 1) and independent claim 16. Claim 1 is representative of this group. The claims of Group I stand or fall together.

GROUP II - Includes dependent claims 2 to 7, which depend on claim 1. If Claim 1 of Group I is found patentable, then so should the claims of Group II. Moreover, the Group II claims relate to those claims that are limited to "a third component as a series of regularly spaced third trains of regularly spaced pulses". Claim 2 is representative of this group. The claims of Group II stand or fall together.

ARGUMENT

This appeal turns on whether the prior art teaches a muscle stimulator that applies "bursts" of stimulating pulses, wherein each burst is a continuous train of low-frequency pulses superimposed by multiple trains of high-frequency pulses.

The limitations of independent claim 1 at issue in this appeal are:

- "regularly spaced bursts of pulses"
- "each burst including a first component as a first continuous train of regularly spaced pulses and a second component as a series of regularly spaced second trains of regularly spaced pulses", and
- "the spacing between successive pulses in the second pulse trains being less than the spacing between successive pulses in the first pulse train."

Cywinski and Campos (the references applied to reject the claims) do not disclose a muscle stimulator applying pulses that are arranged as regularly spaced "bursts". The

references also do not teach individual bursts formed of a continuous low-frequency pulse train and a plurality of high frequency pulse trains.

GROUP I – STIMULATOR APPLYING SPACED BURSTS WHERE EACH BURST HAS FIRST AND SECOND PULSE TRAINS

The rejections of claim 1 of Group I as being anticipated by and obvious in view of Cywinski (US Patent 5,350,415) and by Campos (5,097,833) should be reversed.

The Group I claims, as represented by independent claim 1, state:

An electrical muscle stimulator comprising:

means for generating a predetermined stimulating signal,
and

means for applying the signal to a muscle,

wherein **the signal comprises a series of regularly spaced bursts of pulses with each burst including a first component as a first continuous train of regularly spaced pulses and a second component as a series of regularly spaced second trains of regularly spaced pulses**, the second component being combined with the first component and **the spacing between successive pulses in the second pulse trains being less than the spacing between successive pulses in the first pulse train.** (emphasis supplied).

The Group I claims require "a series of regularly spaced bursts of pulses", such that each burst is spaced apart from the other bursts. Each burst is a grouping of pulses, as is shown in Figure 1.

The specification describes the series of bursts as alternating periods of grouped pulses and periods having no pulses. *See e.g.*, Spec. p. 9, lns. 1-15 ("bursts of pulses are applied for "on" times of ten seconds separated by "off" times of fifty seconds."). The

dictionary definition of "burst" is: "to appear or disappear suddenly"; "to make an abrupt beginning"; "a sudden intense outbreak"; "a brief, intense, or violent effort". Webster's Third New International Dictionary p. 301 (1993). The dictionary definition of "burst" is consistent with the use of the term in the specification to mean a periodic group of pulses that are separated from each other.

A continuous pulse stream (as is disclosed in Cywinski and Campos) is not a "series of regularly spaced bursts of pulses."

The claims further require that each burst has a first component and a second component. The first burst component is a continuous pulse train. The second component is "a series of regularly spaced second trains of regularly spaced pulses". The spacing between pulses in the second trains is less than the spacing between pulses in the first train. Figure 1 shows an exemplary burst having first and second components, as well as a third component (which is the subject of the Group II claims).

A. CYWINSKI DOES NOT ANTICIPATE OR RENDER OBVIOUS ANY CLAIM

Cywinski discloses a continuous pulse train that is applied for muscle stimulation. Cywinski's continuous pulse train has a varying repetition rate which includes: a low frequency component (impulse intervals (IPI) of 120 to 200 milliseconds); a second higher frequency component (IPI of 60-80 milliseconds), and a third still higher frequency component (IPI of 10-20 milliseconds). Cywinski, col. 5, lns. 15 to 37.

1. Cywinski Does Not Disclose Bursts Of Pulses

The Cywinski pulse pattern is continuous and is not a series of spaced apart bursts. Cywinski at column 5, line 15 refers to a "continuous low-rate firing activity",¹ at column 5, line 21 refers to "continuously repetitive slow pulse activity", and at column 8, line 37 again refers to "a continuous low-rate firing activity". That Cywinski periodically increases the repetition rate of the pulse train does not change the fact that the pulse train is continuous.

The continuous train of pulses disclosed in Cywinski is contrary to the claimed "regularly spaced bursts of pulses." Accordingly Cywinski teaches away from the present invention and does not support the obviousness rejection. *In re Geisler*, 43 U.S.P.Q.2d 1362 (Fed. Cir. 1997) ("a prima facie case of obviousness can be rebutted if the applicant . . . can show "that the art in any material respect taught away" from the claimed invention."). The rejections for anticipation and obviousness based on Cywinski should be reversed because Cywinski does not teach or suggest applying a series of regularly spaced bursts of pulses.

The PTO statement in the Final Action at page 5 that "Cywinski and Campos disclose a continuous train/series of at least four bursts of pulses" is an incorrect and unsupported characterization of the continuous pulse streams disclosed in those references. This PTO statement is made without citation to any text or figure in Cywinski or Campos. The only portion of Cywinski (col. 5 starting at line 20) that is

¹ Cywinski stops the continuous train of pulses applied to the patient after a predetermined treatment period. Cywinski at column 8, lines 10 to 14, states that the system stops the pulse generating means to stop the entire stimulator treatment until the next manual reset application after counting (in the described example) fifty clock pulses.

cited in the entire Action refers to "a continuously repetitive slow pulse activity" on which is superimposed "a rectangular-like rate modulation with exponential rise and fall." This cited section of Cywinski does not suggest bursts of pulses. The Action makes no reference to any particular section of Campos. for this reason, the manner in which Campos is applied to reject the claims is at best unclear.

2. Cywinski Does Not Disclose Bursts Having First and Second Pulse Trains

Cywinski does not teach a signal burst formed of multiple trains of high frequency (second component) pulses and a continuous train of low frequency pulses (first component). The pulse pattern envisaged by Cywinski is a continuous relatively low frequency train of pulses into which a series of relatively higher frequency components are interleaved at regular intervals. The higher frequency components starting with three or four pulses with a relatively low impulse intervals (IPI) are followed by a slightly larger number of pulses with a relatively higher IPI. There is nothing to suggest that the Cywinski signals are spaced apart bursts with each of the bursts incorporating two components one of which is continuous through the bursts and the other of which is made up of a series of higher frequency pulse trains. Accordingly, the anticipation and obviousness rejections of the Group I claims should be reversed with respect to Cywinski.

B. CAMPOS DOES NOT ANTICIPATE OR RENDER OBVIOUS ANY CLAIM

The Action does not explain how Campos allegedly discloses the invention recited in the claims of this application. Accordingly, no case for anticipation or obviousness has been made out with respect to Campos. Failure to make out a prima facie case for anticipation is alone a sufficient reason to reverse the rejection based on Cywinski.

Further, Campos describes a muscle stimulator that applies a continuous train of pulses to the patient. Campos, as does Cywinski, discloses a continuous pulse train having irregular spacing between pulses. Campos at col. 8, lns. 54-69, discloses that pulses in a continuous train may be paired together as shown in Figure 12D of Campos. Campos does not suggest that pulses should be applied to the patient as spaced apart bursts of pulses, and certainly does not suggest an individual burst having a first continuous pulse train and multiple superimposed pulse trains. Accordingly, the rejections of anticipation and for obviousness based on Campos should be reversed for many of the same reasons stated above for Cywinski.

GROUP II – THIRD PULSE TRAIN IN THE BURST

Cywinski and Campos do not disclose features recited in the Group II claims (as represented by claim 2) of: “a third component as a series of regularly spaced third trains of regularly spaced pulses”.² There is no suggestion in Cywinski and Campos of

² If the rejection of the Group I claims are reversed then it is unnecessary to separately address Group II.

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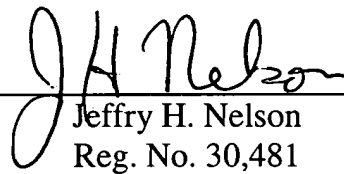
superimposing a third pulse train on the first and second pulse trains in an individual burst. The rejection of the Group II claims should be reversed.

CONCLUSION

The application is in clear condition for allowance. Early reversal of the Final Rejection and passage of the subject application to issue are earnestly solicited.

Respectfully submitted,

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APPENDIX
CLAIMS ON APPEAL

1 (Rejected). An electrical muscle stimulator comprising:

means for generating a predetermined stimulating signal, and

means for applying the signal to a muscle,

wherein the signal comprises a series of regularly spaced bursts of pulses with each burst including a first component as a first continuous train of regularly spaced pulses and a second component as a series of regularly spaced second trains of regularly spaced pulses, the second component being combined with the first component and the spacing between successive pulses in the second pulse trains being less than the spacing between successive pulses in the first pulse train.

2 (Rejected). A stimulator as claimed in claim 1, wherein each burst of pulses includes a third component as a series of regularly spaced third trains of regularly spaced pulses, the third component being combined with the first and second components, and the spacing between successive pulses in the third pulse trains being less than the spacing between successive pulses in the second pulse trains.

3 (Rejected). A stimulator as claimed in claim 2, wherein each burst of pulses consists of the same number of second and third pulse trains.

4 (Rejected). A stimulator according to claim 3, wherein each third pulse train immediately precedes a respective second pulse train.

5 (Rejected). A stimulator as claimed in claim 2, wherein each third train consists of two pulses.

6. (Rejected) A stimulator as claimed in claim 3, wherein each third train consists of two pulses.

7(Rejected). A stimulator as claimed in claim 4, wherein each third train consists of two pulses.

8 (Rejected). A stimulator as claimed in claim 2, wherein the first train consists of pulses at 500 milliseconds intervals, each second train consists of pulses at 20 milliseconds intervals, and each third train consists of pulses of intervals of 12 milliseconds or less.

9 (Rejected). A stimulator as claimed in claim 8, wherein each second of the pulse train consists of pulses timed at 0, 8, 20, 40, 60, 80, 100 and 500 milliseconds.

10 (Rejected). A stimulator as claimed in claim 8, wherein each second of the pulse train consists of pulses timed at 0, 8, 28, 48, 68, 88, 108 and 500 milliseconds.

11 (Allowed). A electrical muscle stimulator comprising:

means for generating a predetermined stimulating signal, and

means for applying the signal to a muscle,

wherein the signal comprises a series of regularly spaced bursts of pulses with each burst including a first component as a first continuous train of regularly spaced

pulses and a second component as a series of regularly spaced second trains of regularly spaced pulses, the second component being combined with the first component and the spacing between successive pulses in the second pulse trains being less than the spacing between successive pulses in the first pulse train, and

a battery powered hand-held unit with a single input/output connector, a battery charger, an electrode connector connected to said means for applying, and a computer connection cable, the battery charger, electrode connector and computer connection cable each being adapted to be connected to the single input/output connector such that the electrode connector cannot be connected to the hand-held unit if the hand-held unit is connected either to the battery charger or the computer connection cable.

12 (Rejected). A stimulator as claimed in claim 1, further comprising means for enabling a user to adjust the amplitude of the pulses.

13 (Allowed). A stimulator as claimed in claim 11, wherein the hand-held unit is programmable and is adaptable to be controlled by computer-generated signals applied to the single input/output connector to adjust the width of the pulses.

14(Allowed). A stimulator as claimed in claim 11, wherein the hand-held unit further comprises means for storing patient treatment records data.

15(Allowed). A stimulator as claimed in claim 14, further comprising means for outputting said patient treatment records data to the single input/output connector.

16 (Rejected). A method for electrically stimulating a muscle in which a stimulating signal is applied to the muscle, comprising:

a) generating the stimulating signal, the signal comprising a series of regularly spaced bursts of pulses with each burst including:

(i) a first component as a first continuous train of regularly spaced pulses, and

(ii) a second component as a series of regularly spaced second trains of regularly spaced pulses, wherein the second component is combined with the first component and the spacing between successive pulses in the second pulse trains is less than the spacing between the successive pulses in the first train, and

b) applying the stimulating signal to the muscle.